

the distribution of uncertified and possibly unsafe shellfish in interstate commerce. Without the ICSSL, the effectiveness of the NSSP would be nullified. The ICSSL is also used to identify U.S. shellfish dealers eligible to obtain health certificates and export to certain countries or regions.

FDA has been collecting information to construct the ICSSL since 2001. FDA is seeking to add one new data field to the Form FDA 3038, the “FDA Establishment Identifier” (FEI number). The FEI number is a unique number assigned by FDA to identify FDA-regulated facilities. FDA will explore whether the FEI can be used to retrieve data on shellfish dealers from existing FDA systems, which could reduce the number of required data elements that firms have to submit on Form FDA 3038.

The information collection also includes providing certain documents demonstrating compliance with the NSSP. When a competent authority in another country conducts an evaluation to determine whether the U.S. food safety control measures for molluscan shellfish are equivalent to their system

of controls, the competent authority may require FDA to provide information and records demonstrating compliance with the provisions of the NSSP. Only those firms that comply with the NSSP would be permitted to export molluscan shellfish to a country whose competent authority determined that the U.S. system of controls is equivalent to their own controls. If approved, FDA will use this information to support the export of U.S. shellfish to countries whose competent authorities have determined the U.S. system of food safety controls to be equivalent to their own system of controls by demonstrating that the exporter is in compliance with the U.S. system of controls specified in the NSSP.

For example, to implement the European Commission’s (EC) determination that the U.S. system of food safety controls for raw bivalve molluscan shellfish is equivalent to the European Union’s (EU) system of controls, the EC is requiring FDA to provide documentation collected from NSSP-participating shellfish control authorities with firms seeking to export raw molluscan shellfish to the EU. This

documentation includes, but is not limited to:

- A list of growing areas with an Approved classification;
- the most recent sanitary survey for each growing area with an Approved classification; and
- the most recent inspection report for each firm seeking to export shellfish to the EU.

The examples above are illustrative. Some competent authorities may require additional information to conduct an equivalence assessment or to implement an equivalence determination, or both. We plan to provide respondents with information about the specific documentation that is required for each equivalence assessment. For those competent authorities that recognize the U.S. system as equivalent, additional documentation may be needed to implement that determination.

Description of Respondents:

Respondents to this collection are participating State and local regulatory agencies and foreign nations.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of Interstate Shellfish Dealer’s Certificate	3038	40	57	2,280	0.10 (6 minutes)	228
Submission of Other Records Related to Participation in the NSSP.	N/A	13	1	13	0.25 (15 minutes)	3.25
Total						231.25

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. This estimate is based on our experience with this information collection and the number of certificates received in the past 3 years, which has remained constant.

Dated: October 28, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Biodefense Science Board (NBSB or the Board) is authorized under Section 319M of the Public Health Service (PHS) Act, as added by section 402 of the Pandemic and All-Hazards Preparedness Act of 2006 and amended by section 404 of the Pandemic and All-Hazards Preparedness Reauthorization Act. The Board is governed by the Federal Advisory Committee Act (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees. The NBSB provides expert advice and guidance on scientific, technical, and other matters of special interest to the Department of Health and Human Services (HHS) regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. Authority to manage and operate the NBSB, including to receive

advice and recommendations from the Board, has been delegated by the Secretary of HHS to the Assistant Secretary for Preparedness and Response (ASPR). The NBSB will meet in public (virtually) on December 16, 2021, to provide advice and recommendations to ASPR regarding the development of the 2023–2026 National Health Security Strategy and to discuss other matters of current importance for public health emergency preparedness, response, and recovery. A more detailed agenda will be available on the NBSB meeting website <https://www.phe.gov/nbsb>.

Procedures for Public Participation: Members of the public may attend the meeting via a toll-free phone number or Zoom teleconference, which requires pre-registration. The meeting link to pre-register will be posted on the meeting website <https://www.phe.gov/nbsb>. Members of the public may provide written comments or submit

questions for consideration by the NBSB at any time via email to NBSB@hhs.gov.

Additionally, the NBSB invites those who are involved in or represent a relevant biodefense or health security industry, serve as faculty or conduct research at an academic institution, occupy a relevant health profession, or work for a hospital system or health care consumer organization; or those who serve in a state, Tribal, territorial or local government agency to request up to seven minutes to address the Board in person via Zoom. Requests to provide remarks to the NBSB during the public meeting must be sent to NBSB@hhs.gov by midnight on October 10, 2021. In that request, please provide the name, title, and position of the individual who will be speaking and a brief description of the planned topic. Presenters who are selected for the public meeting will have audio only during the meeting, thoughlides, documents, and other presentation material may be sent ahead; those will be provided directly to the board members. Topics and presentations with an obvious commercial bias, to include any form of advertising, marketing, or solicitation, will not be accepted.

FOR FURTHER INFORMATION CONTACT:
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Dawn O'Connell,

Assistant Secretary for Preparedness and Response.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Domestic Violence Prevention: Forensic Healthcare Services

Announcement Type: New.

Funding Announcement Number:
HHS-2022-IHS-FHC-0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number:
93.653.

Key Dates

Application Deadline Date: February 2, 2022.

Earliest Anticipated Start Date: March 21, 2022.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for grants that

will develop and/or expand Forensic Healthcare (FHC) services. This program was first established by the Omnibus Appropriations Act of 2009, Public Law 111-8, 123 Stat. 524, 735, as a component of the Domestic Violence Prevention Initiative, and continued in the annual appropriations acts since that time. This program is authorized under the Snyder Act, 25 U.S.C. 13; and the Indian Health Care Improvement Act, 25 U.S.C. 1665a, 1665m. This program is described in the Assistance Listings located at <https://sam.gov/content/home> (formerly known as Catalog of Federal Domestic Assistance) under 93.653.

Background

The Division of Behavioral Health (DBH) serves as the primary source of national advocacy, policy development, management and administration of behavioral health, alcohol and substance abuse, and family violence prevention programs. Domestic and sexual violence including child maltreatment are a public health concern among the American Indian/Alaska Native (AI/AN) population. American Indians and Alaska Natives experience high rates of sexual violence according to a 2016 publication from the Department of Justice. Previously, forensic health care functions were funded under Purpose Area 2 of the Domestic Violence Prevention (DVP) program, formerly known as the Domestic Violence Prevention Initiative. This announcement separates forensic health care functions into a distinct program. The FHC program will address access to health care needed for AI/AN victims of domestic and sexual violence. The IHS supports comprehensive efforts to develop and/or expand FHC services to provide treatment, intervention, and prevention in order to address the needs of victims impacted by domestic violence, sexual assault, stalking, sexual exploitation/human trafficking, and child maltreatment. The FHC program is aligned with the national DVP goals, <https://www.ihs.gov/dvpi/aboutdvp/>.

Purpose

The purpose of this IHS grant is to provide access to treatment for AI/AN victims of domestic and sexual violence by supporting the development of and/or expansion of FHC services that are culturally appropriate and trauma-informed. The intent is to impact FHC services in each IHS Area (provided by Tribes, Tribal organizations and Urban Indian organizations). This also includes promoting treatment, intervention, and prevention efforts for the social, spiritual, and emotional well-

being of victims, including victims of child maltreatment. To address domestic and sexual violence, including victims of sexual exploitation/human trafficking, applicants are encouraged to use Multidisciplinary Team (MDT) and Sexual Assault Response Team (SART) approaches. Using these types of team approaches is crucial—especially among local, state, and Federal agencies that includes health care providers, law enforcement, child protective services, social services, legal services, domestic violence coalitions, behavioral health services, and victim advocacy. The MDT/SART are community-based approaches in responding to sexual assault, intimate partner violence, and sexual abuse victims. Without the advantage of a team approach method, a program is more likely to fail. Improving collaboration through formal inter-agency agreements can improve the response time for sexual assault victims.

II. Award Information

Funding Instrument—Grant

Estimated Funds Available

The total funding identified for fiscal year (FY) 2022 is approximately \$2,500,000. Individual award amounts for the first budget year are anticipated to be \$250,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 10 awards will be issued under this program announcement with up to one award set aside for an eligible Urban Indian organization.

Period of Performance

The period of performance is for 5 years.

III. Eligibility Information

1. Eligibility

To be eligible for this new FY 2022 funding opportunity, applicants must be one of the following as defined by 25 U.S.C. 1603:

- A federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14). The term "Indian Tribe" means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or group, or regional or village corporation as defined in or established pursuant to the